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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,131	11/13/2003	Mirko Lehmann	SMB-PT036 (PC 00 320 H US	5548
3624 7590 03/08/2007 VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1744	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/009,131

Applicant(s)

LEHMANN ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/14/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed 3/14/05 has been considered and made of record.

Specification

3. The disclosure is objected to because of the following informalities:
The "Brief Description of the Drawings" does not reference Figure 11.
Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 2 and 5-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Modlin et al. (WO 00/05336).

With respect to claim 1, the reference of Modlin et al. discloses a device that includes at least one receptor (150); one or more measuring devices (See page 8, lines 21-23); a movable separation element (152) which borders a reaction space at the bottom of the receptor (15) and forms a reservoir space above the separation element (152) (See Figure 2). As shown in Figure 2, the reservoir space is “an order of magnitude greater” than the volume of the reaction space. The separation element can be moved through an up and down motion (See page 9, line 27, to page 10, line 4).

With respect to claim 2, the separator element displaces a partial volume of liquid that covers the cell culture on the bottom of the receptor (See page 8, line 24, to page 9, line 5).

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With respect to claim 5, the separator (152) extends into receptacle (150) to define the two portions. An annular gap formed by the space between the outer surface of the separator and the inner surface of the receptacle provides fluid communication between the two portions.

With respect to claim 6, one or more measuring devices (See page 8, lines 21-23) are positioned in the area of the reaction space or bottom of the receptor.

With respect to claim 7, the separating element (152) can move between positions (See page 9, line 27, to page 10, line 4).

With respect to claim 8, the surface of the separator (152) that faces the bottom of the receptor (150) meets the structure of the claimed cover.

With respect to claim 9, the separating element (152) can be inserted from above the receptacle (150).

With respect to claim 10, the distance between the bottom of the receptor and separator is adjustable (See page 9, line 27, to page 10, line 4).

With respect to claim 11, the separating element (152) is in the shape of a hand stamp (See Figure 2).

With respect to claims 12 and 13, the separator element provides channel for fluid displacement that include an annular gap or channels (See page 9, lines 2-5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 14-16, 18, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modlin et al.(WO 00/05336).

The reference of Modlin et al. has been discussed above.

With respect to claim 14, while the reference is silent with respect to a structure for reducing the presence of gas bubbles, it would have been well within the purview of one having ordinary skill in the art to provide the separator of a construction such that gas bubbles do not collect within the chamber and alter the sensor results.

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With respect to claims 15 and 16, the use of positioning detents would have been well within the purview of one having ordinary skill in the art so as to ensure the correct positioning of the separator within the receptacle during the measuring steps.

With respect to claim 18, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum volume of the reservoir chamber relative to the reaction chamber while reducing evaporation and enhancing cell culture.

With respect to claim 20, the exact position of the detection devices within the system would have been obvious based merely on the specifics of the type of detection to be performed relative to the reagents within the reaction space.

With respect to claim 22, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum material of construction of the separator device while maintaining the efficiency of the detection system.

12. Claims 3, 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modlin et al.(WO 00/05336) in view of Wolf et al.(US 6,376,233).

The reference of Modlin et al. has been discussed above.

With respect to the construction of the bottom of the receptacle device required of claims 3, 4 and 19, the reference of Wolf et al. discloses that it is conventional in the art to construct a culture well with a plurality of recesses that include a multiplicity of sensors (See Figure 1).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the receptacle device of the reference of Wolf et al. with a separator design disclosed by the primary reference for the known and expected of reducing the volume of liquid contacting the reaction and/or detection zone as disclosed by the reference of Modlin et al.

13. Claims 17, 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modlin et al.(WO 00/05336) in view of Harris et al.(US 5,468,605).

The reference of Modlin et al. has been discussed above.

With respect to pipette interface required of claims 17, 24 and 25, the reference of Harris et al. discloses that it is known in the art to interface a microchamber holding a cell culture with a pipette structure (See Figure 2).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the separator of the reference of Modlin et al. with a pipette interface for the known and expected result of allowing the microchamber of cells to be perfused with a test medium.

With respect to the filter of claim 21, the reference of Harris et al. also discloses the use of a filter structure (117, 120) for holding the cells within the chamber (See Figure 2).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with a filter structure for the known and expected result of facilitating the containment of the cells within the reaction space.


Conclusion

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB